

## REMARKS

Entry of the foregoing amendments is respectfully requested.

### Summary of Amendments

Upon entry of the foregoing amendments, claim 15 is amended, claim 21 is cancelled and claim 35 is added, whereby claims 15-35 will be pending, with claims 15, 26 and 34 being independent claims. Support for the new and amended claims can be found throughout the present specification (and in particular, at page 6 thereof) and in the original claims.

Applicants emphasize that the amendment to claim 15 is without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute claim 15 in its original, unamended form in one or more continuation and/or divisional applications.

### Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Supplemental Information Disclosure Statement filed August 23, 2007 by returning a signed and initialed copy of the Form PTO-1449 submitted therein.

Applicants also note with appreciation that the Examiner has withdrawn the previous rejections over Pan et al., U.S. Patent No. 5,912,007 and Lapidus, U.S. Patent No. 5,543,148.

Claims 15-21 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Takeuchi et al., U.S. Patent No. 5,624,962 (hereafter "TAKEUCHI").

Claims 15-21 are also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Busciglio, U.S. Patent No. 4,748,022 (hereafter “BUSCIGLIO”).

Claims 15-20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Thut et al., U.S. Patent No. 5,505,922 (hereafter “THUT”).

Claims 15-34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over THUT.

**Response to Office Action**

Withdrawal of the rejections of record is respectfully requested, in view of the foregoing amendments and the following remarks.

***Response to Rejection of Claims under 35 U.S.C. § 102(b) over TAKEUCHI***

Claims 15-21 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by TAKEUCHI.

Applicants respectfully (and strongly) disagree with the Examiner in this regard. At any rate, it is evident that the subject matter of independent claim 15 submitted herewith is not anticipated by TAKEUCHI. In particular, claim 15 now additionally recites that the composition comprises about 0.1 g to 10 g of antihistamine per 1 g of local anesthetic. TAKEUCHI clearly does not disclose any ratio of antihistamine and local anesthetic and for this reason alone, is unable to anticipate the subject matter of claim 15 and any of the claims dependent therefrom.

Applicants submit that for at least the foregoing reasons, the rejection of claims 15-20 under 35 U.S.C. § 102(b) over TAKEUCHI should be withdrawn, which action is respectfully requested.

***Response to Rejection of Claims under 35 U.S.C. § 102(b) over BUSCIGLIO***

Claims 15-21 are also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by BUSCIGLIO.

Applicants respectfully disagree with the Examiner in this regard as well. At any rate, it is pointed out that amended claim 15 recites, *inter alia*, that the composition has a pH of about 3.0 to 7.5. In contrast, the compositions of BUSCIGLIO are required to have a pH of 8-9 (see, e.g., abstract, col. 4, lines 48-49 and claim 1 of BUSCIGLIO).

For at least the foregoing reason, BUSCIGLIO fails to anticipate the subject matter of any of claims 15-20, wherefore withdrawal of the rejection under 35 U.S.C. § 102(b) over BUSCIGLIO is warranted and respectfully requested as well.

***Response to Rejection of Claims under 35 U.S.C. § 102(b) over THUT***

Claims 15-20 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by THUT.

Applicants respectfully disagree with the Examiner in this regard as well but note that amended independent claim 15 submitted herewith additionally recites the subject matter of (cancelled) claim 21. Claim 21 has not been rejected as anticipated by THUT (for good reasons), wherefore there is no basis for maintaining the rejection of instant claims 15-20 for this reason alone.

***Response to Rejection of Claims under 35 U.S.C. § 103(a)***

Claims 15-34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over THUT. The rejection concedes that THUT fails to disclose the osmotic pressure ratio and the amount of antihistamine per anesthetic recited in the rejected claims but essentially alleges that these features are merely the result of routine optimizations which do not require more than ordinary skill.

Applicants respectfully traverse this rejection. In particular, the Examiner is reminded that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

In this regard, it is pointed out that THUT fails to teach or suggest using a combination of any amide-type local anesthetic and any antihistamine-like anesthetic such as benadryl. Specifically, one of ordinary skill in the art will understand that the statement in col. 3, lines 47-49 of THUT on which the present rejection appears to be based, i.e., that the various types of local anesthetics mentioned in the preceding sentence “can be present in the anesthetic pharmaceutical combination alone or as a mixture of two or more thereof” is not more than a mere boilerplate statement which neither teaches or suggests that using a combination of two or more of these local anesthetics, let alone a combination of an amide-type local anesthetic and an antihistamine-like anesthetic, is associated with any advantage. This is supported by the fact that THUT fails to disclose any combination of two or more local anesthetics, let alone demonstrates that using such a combination provides better results than using only one anesthetic.

It further is pointed out that none of the claims of THUT which recite specific local anesthetics (claims 3 and 11) mention an antihistamine-like anesthetic (let alone benadryl), which indicates that antihistamine-like anesthetics are not particularly preferred for the purposes described by THUT.

Applicants submit that for at least all of the foregoing reasons, THUT provides no motivation whatsoever for one of ordinary skill in the art to employ an amide-type local anesthetic in combination with an antihistamine-like anesthetic, let alone to optimize the weight ratio of these two types of anesthetics.

Applicants also respectfully disagree with the allegation set forth at page 6, second paragraph of the present Office Action. This allegation is merely a conclusory statement which is not supported by any written (or other) evidence at all, let alone evidence which shows that there is a well-known relationship between the isotonicity of a composition and the ability of the composition to diffuse into the patient's system.

In view of the foregoing, it is submitted that THUT is unable to render obvious the subject matter of any of the claims submitted herewith, wherefore the rejection of claims 15-34 under 35 U.S.C. § 103(a) over THUT is without merit and withdrawal thereof is respectfully requested.

### CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,  
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